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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,857	09/30/2003	Stephen J. Williams	50225-8032.US05	7646
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PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			EXAMINER WATTS, ALLISON LEIGH	
			ART UNIT	PAPER NUMBER
			1753	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/676,857

Applicant(s)

WILLIAMS ET AL.

Examiner

Allison L. Watts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/6/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey in view of Parce et al. and Krivankova et al.

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As to Claim 23, Ramsey disclose a microfluidic system used for electrophoretic separation of charged sample components in a dilute sample (column 3, lines 2-14), the system comprising: a channel network formed in a substrate (column 8, lines 37-38) including a separation channel (24) (column 7, lines 64-67) with first and second side channels (28, 30) intersecting the separating channel, the separation channel divided into: an upstream channel region (26) upstream of the first side channel (28); a sample-volume channel region (42) between the two side channels (28, 30); a downstream separation channel region (34) downstream of the second side channel (30); upstream and downstream reservoirs (12, 20) communicating with the ends of the separation channel (24); first and second reservoirs (14, 16) communicating with the first and second side channels (28, 30); electrodes contacting liquid in all the reservoirs; and a control unit (46) having a power source connected to the electrodes (column 6, line 60 through column 7, line 27; column 7, line 64 through column 8, line 20). Ramsey also disclose providing trailing and leading edge electrolytes for sample stacking (Figure 1; column 18, lines 30-44; column 20, lines 22-29)

Ramsey discloses using trailing and leading edge electrolytes, but does not disclose them being in the upstream and downstream regions, respectively. Ramsey also does not disclose the sample volume region containing the sample.

Parce et al. disclose a microfluidic system used for electrophoretic separation of charged sample components in a dilute sample (column 3, lines 51-59), the system comprising: a channel network formed in a substrate (column 4, lines 51-60) including a separation channel (502) with first and second side channels (504, 508) intersecting the

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separating channel, dividing the separation channel into: an upstream channel region upstream of the first side channel; a sample-volume channel region between the two side channels containing the dilute sample (the channel portion between intersections 506 and 508); a downstream separation channel region downstream of the second side channel; upstream and downstream regions containing an electrolyte with a different conductivity than the sample buffer solution (Figures 5A-5E; column 13, line 18 through column 15, line 62).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the channel system of Ramsey by supplying the sample to the sample-volume region and surrounding the sample with upstream and downstream electrolyte solutions of a different conductivity than the sample buffer solution because Ramsey discloses using trailing and leading edge electrolytes and the set-up of Parce et al. is the standard set-up for this type of analyte stacking method.

Ramsey discloses a trailing edge electrolyte, but does not disclose it containing a titratable species,

Krivankova disclose an isotachopheresis method providing a trailing and leading edge electrolytes, with the trailing edge electrolyte containing a titratable species of a concentration selected to permit the charged sample components, upon application of a voltage, to stack into a small sample volume before hydroxyl or hydrogen ion migration through the sample-volume region is effective to overtake the charged sample components (page 31 through page 33).

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the trailing edge electrolyte of Ramsey by providing a titratable species as disclosed by Krivankova because it will meet the conditions for isotachophoresis and effective stacking of analytes.

As to Claim 24, Ramsey disclose the upstream channel region including a reservoir (12) and that more advanced systems utilizing additional buffers, such as trailing and leading edge electrolytes, may need additional buffer reservoirs (column 20, lines 22-29), where solutions contained in the reservoirs may be mixed to any desired concentration (column 31, lines 41-51).

Ramsey does not disclose providing a titratable species in a first upstream reservoir and a source of hydroxyl or hydrogen ions in a second upstream reservoir.

Krivankova disclose the need for a specific concentration of a titratable species in the trailing edge electrolyte (Page 31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the upstream reservoirs of Ramsey and provide a trailing edge electrolyte and a source of hydroxyl or hydrogen ions as disclosed by Krivankova because the selection of the concentration of the titratable species in the trailing edge electrolyte is an essential factor in the migration and stacking of the analyte and using the multiple reservoirs of Ramsey would assist in the precise mixing of the trailing edge electrolyte and the titratable species to the desired concentration.

As to Claim 25, Ramsey does not disclose the length of the sample-volume region to that of the downstream separation channel region being between 1:50 to 1:1.

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Gardner v. TEC Systems, Inc. 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984) addresses size adjustments, where the difference between the dimensions of Ramsey and the applicant would not impact the performance of the device.

As to Claim 26, Ramsey discloses providing a control unit connected to the electrodes for applying a voltage (column 7, lines 14-27) in order to measure and dispense a selected amount of solution and mix the solutions in desired concentrations (column 6, lines 31-44 and column 9, lines 7-16), where the concentration of the solution selected may depend on conductivity of the solutions and the channel lengths (column 32, line 8 through column 33, line 12).

Ramsey does not disclose the control unit operable to calculate a selected concentration of titratable species.

Krivankova disclose the need for a specific concentration of a titratable species in the trailing edge electrolyte (Page 31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify control unit calculations disclosed by Ramsey by calculating a specific concentration of titratable species as disclosed by Krivankova because because it will meet the conditions for isotachophoresis and effective stacking of analytes.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 23-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 9, and 12 of U.S. Patent No. 6685813 in view of Ramsey.

As to claim 23, US 6685813 discloses a microfluidic system for separating charged components having a channel network comprising an upstream region containing a trailing edge electrolyte, a sample-volume region containing a dilute sample, a separating region containing a leading edge electrolyte, a first and second side channels, upstream and first side channel reservoirs, and electrodes contacting the liquid in the end of each channel segment and applying a voltage (claims 1 and 12).

US 6685813 does not specifically disclose a downstream reservoir or a second side channel reservoir.

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Ramsey discloses a microfluidic channel system for separation of charged particles (column 3, lines 2-14) and providing a reservoir on each channel end (Figure 1) for storing solutions before transporting them throughout the channel system (column 7, lines 12-14).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system disclosed by US 6685813 by providing reservoirs on the end of each channel as disclosed Ramsey because it allows for storing different solutions in each channel end before distributing it to the other channels.

3. US 6685813 also does not disclose a control unit having a power source connected to the electrodes for applying a voltage.

4. Ramsey further discloses providing a control unit connected to the electrodes for applying a voltage (column 7, lines 14-27).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system disclosed by US 6685813 by providing a control unit as disclosed Ramsey because it allows for control of the electrodes in order to manipulate each solution in each channel end independently.

As to claim 24, US 6685813 discloses a pair of upstream reservoirs, one containing the trailing edge electrolyte and the other containing a source of hydroxyl or hydrogen ions (claim 2).

As to claim 25, US 6685813 discloses the ration of the sample-volume channel length and the separation channel length being between 1:50 to 1:1 (claim 9).

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As to claim 26, US 6685813 discloses selecting a concentration of titratable species in the trailing edge electrolyte based on the ration of channel lengths (claim 3).

US 6685813 does not disclose a control unit operable to make the calculation of the selected concentration of titratable species.

Ramsey discloses providing a control unit connected to the electrodes for applying a voltage (column 7, lines 14-27) in order to measure and dispense a selected amount of solution and mix the solutions in desired concentrations (column 6, lines 31-44 and column 9, lines 7-16), where the concentration of the solution selected may depend on conductivity of the solutions and the channel lengths (column 32, line 8 through column 33, line 12).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of US 6685813 by providing a control unit able to select a concentration of a species as disclosed by Ramsey because it allows for maximizing the separation of charged components.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6818113 B2, US 5869004 A, US 5858187 A, US 5965001 A,

6. US 5880071 A, US 5800690 A, and US 5599432 A.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison L. Watts whose telephone number is (571) 272-


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6640. The examiner can normally be reached on Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALW
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